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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,545	06/30/2003	Jeffrey E. Koziol	40476A	7271

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EXAMINER

BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/608,545

Applicant(s)

KOZIOL, JEFFREY E.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/29/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

1. Applicant's amendment to the specification and to the claims in the Preliminary Amendment filed on December 29, 2003 is acknowledged.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration (emphasis added).

The present application is a straight continuation of Application Number 09/852,846 (= US 6,589,280). As noted above, a Preliminary Amendment was filed December 29, 2003. The Oath/Declaration was filed on June 30, 2003, which is prior to the filing date of the Preliminary Amendment.

Election/Restrictions

3. Applicant's election with traverse of **Lens System**: Species B (multiple lenses) and **Shape of Lens**: Species A (rings-shaped) in the reply filed on June 24, 2004 is acknowledged.

The traversal is on the ground(s) that the species of the claimed invention "*are sufficiently related and should be examined together*" and also that "*the office action provides no reason and/or examples to justify the conclusion that the second Species A and the second Species B are patentably distinct species of the claimed invention*".

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This is not found persuasive because the Examiner required an Election of Species, not a Restriction. As defined in MPEP 808.01(a), for an Election of Species "*it is not necessary to show a separate status in the art or separate classification*". Also, that same section of the MPEP teaches that for a multiplicity of species requiring extensive and/or burdensome search, "*a requirement for an election of species should be made prior to a search*".

Furthermore, the Office Action state: "*should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case*".

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 23-48 and 52-67 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-37 of U.S. Patent No. 6,589,280 (cited in Applicant's IDS). Although the conflicting claims are not identical, they are not patentably

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distinct from each other because the difference between claims 23-48 and 52-67 of the application and claims 1-37 of the patent lies in the fact that the patent claims include many more elements and is thus much more specific. Thus the invention of claims 1-37 is in effect a “species” of the “generic” invention of claims 23-48 and 52-67. It has been held that the generic invention is “anticipated” by the “species”. See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 23-48 and 52-67 are anticipated by claims 1-37 of the patent, it is not patentably distinct from claims 1-37.

Claim Objections

6. Claims 23, 41, 44, 52, and 61 are objected to because of the following informalities:

a. Regarding claim 23, please add --the method-- in front of “comprising” (see line 2).

Appropriate correction is required.

b. Regarding claim 41, please substitute “an first” (see line 4) with --a first--. Appropriate correction is required.

c. Regarding claim 44, please add --internal-- in front of “surfaces” (see line 4). Appropriate correction is required.

d. Regarding claim 52, please add --the method-- in front of “comprising” (see line 2). Appropriate correction is required.

e. Regarding claim 61, please add --corneal-- in front of “surfaces” (see line 4 and line 6). Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 51 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification and/or figures do not disclose/describe a second inner diameter as being about one millimeter larger than a first outer diameter.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 30, 41-48, 59, and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a.** Regarding claim 30, the claimed subject matter renders the claim vague and indefinite.

According to independent claim 23 there are at least 50 lenses, while according to dependent claim 30 there is a first set of at least 20 lenses and a second set of at least 20 lenses ($20 + 20 = 40$). If independent claim 23 requires at least 50 lenses, then dependent claim 30 is indefinite since it requires at least 40 lenses.

- b.** Regarding claim 41, “the main optical axis” (see line 5 and line 10) lacks antecedent basis.

Claims 42-48 depend on claim 41.

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c. Regarding claim 43, “the optical axis of them” (see line 5 and line 10) lacks antecedent basis.

Also, the expression “the optical axis of them” is vague and confusing, rendering claim 43 indefinite.

d. Regarding claim 59, the claimed subject matter renders the claim vague and indefinite.

According to independent claim 52 there are at least 50 lenses, while according to dependent claim 59 there is a first set of at least 20 lenses and a second set of at least 20 lenses (20 + 20 = 40). If independent claim 52 requires at least 50 lenses, then dependent claim 59 is indefinite since it requires at least 40 lenses.

e. Regarding claim 62, “the first and second internal corneal surfaces” (see lines 3-4) lacks antecedent basis.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 23-25, 28-33, 35, 37-46, 48-54, 56, 58-64, 66, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman (US 5,964,748 A; cited in Applicant’s IDS) in view of Grendahl (US 4,906,245; cited in Applicant’s IDS).

Peyman discloses several methods for modifying a live cornea to correct a patient’s vision. One of those methods comprises separating an internal area of the live cornea into first and second internal surfaces to form a corneal flap, removing the corneal flap from the cornea

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(or leaving it hinged), placing at least one ocular material in between said first and second internal corneal surfaces, and replacing the corneal flap (see Figures 41, 42, 45, 46, 49, 54, 57, and 59; see columns 17-22). Peyman further adds that the ocular material could consist of a plurality of ocular implants (see column 18, lines 11-14). The ocular material(s) could be a ring-shaped lens or lenses (see Figures 41, 42, 60, and 61) having a diameter of about 3.0 mm to about 9.0 mm and a thickness of about 20 microns to about 1000 microns (see column 17, lines 32-41). Said lens or lenses has a refractive index different or similar to the one of the cornea (see column 17, line 66 to column 18, line 3; column 19, lines 4-9).

Peyman does not particularly disclose the use of at least 50 microscopic lenses. However, Peyman teaches that the ocular implant could be replaced with a plurality of solid or semi-solid implants at selected locations (emphasis added) within pocket of cornea in order to improve/correct the patient's hyperopia or myopia condition (see column 18, lines 11-14; see whole document). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a plurality (e.g., 2 or 50) of microscopic lenses at different locations in the cornea in order to improve/correct the patient's hyperopia or myopia condition. Also, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the invention with either 2 or 50 lenses since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Peyman does not particularly disclose the claimed lens thickness of about 2-3 microns. However, Peyman also discloses that his/her method could be performed "without modifying the curvature of the cornea" (see column 21, lines 12-16 and lines 59-67; column 22, lines 38-42)

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and also that the lens (or lenses) is “very thin, i.e., as thin as paper or thinner” in order to retain the original shape of the exterior surface of the cornea even after the ocular implant or material is inserted into the cornea (see column 22, lines 38-42). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a microscopic lens with a thickness as claimed in order to retain the original shape of the exterior surface of the cornea even after the ocular implant or material is inserted into the cornea. Also, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the lenses with a particular diameter (e.g., about 1mm) and/or thickness (e.g., about 2-3 microns thick) since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Peyman does not particularly disclose arranging the lenses in concentric circles (but see Figure 46). However, Grendahl teaches arranging lens elements in a concentric circle in order to form multifocal vision (see Figures; whole document). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of arranging lens elements in a concentric circle, as taught by Grendahl, with the invention of Peyman, in order to form multifocal vision.

13. Claims 26, 27, 34, 36, 47, 55, 57, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman (US 5,964,748 A; cited in Applicant’s IDS) as applied to claims 23, 25, 33, 46, 52, 56, and 64 above, and further in view of Kaufman (US 6,228,113; cited in Applicant’s IDS).

Peyman does not particularly disclose the claimed diopter power of the lenses. However, Kaufman teaches using 60 lenses with power intervals from +5D to -5D at 0.25D intervals in order to improve/correct a patient's visual disorder (see column 3, lines 30-45). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using 60 lenses with power intervals from +5D to -5D at 0.25D intervals, as taught by Kaufman, with the method of Peyman, in order to improve/correct a patient's visual disorder. Also, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the lenses with a particular dioptric/diopter power (e.g., +1 to +3) since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Nigam (US 6,102,946) and Peyman (US 6,702,807).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

September 15, 2004

A handwritten signature consisting of stylized, overlapping loops, likely representing the initials JGB.A handwritten signature in cursive script, likely belonging to David H. Willse.

David H. Willse
Primary Examiner